UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

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In re INTUNIV ANTITRUST LITIGATION

Civil Action No. 16-cv-12396-ADB (Indirect)

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MEMORANDUM AND ORDER

BURROUGHS, D.J.

This case involves allegations that the Defendants settled patent litigation over the ADHD drug Intniv on anticompetitive terms. The Indirect Purchaser Plaintiffs ("IPPs") are parents and caretakers who purchased Intuniv or generic Intuniv for a child's or ward's medical needs. The IPPs claim that the Defendants engaged in sham patent litigation over Intuniv, and then settled that litigation on terms that delayed competition for both brand Intuniv, manufactured by Shire, and generic Intuniv, manufactured by Actavis.

Before the Court are the IPPs' motion for a protective order and to quash discovery of their children's and wards' ("Minors") medical records and Defendants Shire and Actavis' joint motion to compel discovery of the Minors' medical records. [ECF Nos. 114, 116]. The IPPs

¹ The IPPs have moved for certification of a "Nationwide Consumer Class" comprised of, "For the period beginning November 15, 2012, to the present: (A) all persons who purchased brand or generic Intuniv in the United States for personal or household use, and who paid the purchase price themselves; and (B) all persons covered by commercial health insurance who purchased brand Intuniv in the United States for personal or household use, and who paid some of the purchase price pursuant to a co-payment or co-insurance provision," with certain exclusions. See [ECF No. 146 at 1–2].

also request fees and costs. [ECF No. 114-1 at 17–18]. For the reasons explained below the motions are DENIED in part and GRANTED in part.

I. DISCUSSION

The Defendants have been attempting to obtain discovery since November 2017 as to the factors that influenced the IPPs' selection of Intuniv, including potential alternative treatments and price. The IPPs have resisted discovery into the Minors' medical, pharmaceutical, and health insurance records (collectively "medical records") on grounds of irrelevance, undue burden, and privilege. The IPPs produced heavily redacted pharmacy records to demonstrate that they purchased branded or generic Intuniv but declined to make additional productions, provide complete responses to interrogatories, or authorize non-parties to produce medical records.

The IPPs request that the Court quash a third-party subpoena served on Dr. Steven J. Auster, a medical service provider in this district, issue a protective order prohibiting the Defendants from further prosecution of non-party subpoenas issued to the Minors' healthcare providers, and order the Defendants to pay their fees and costs. Conversely, the Defendants request an order requiring the IPPs to: (i) produce executed authorizations pursuant to Actavis' Demand for Authorizations ("DFA") to allow the Defendants to obtain the IPPs' medical records, see [ECF No. 118-5]; (ii) provide full responses to Shire's Interrogatories Nos. 1–3, 9, and 10, see [ECF No. 118-3]; (iii) produce documents responsive to Shire's Requests for Production ("RFP") Nos. 1–4, see [ECF No. 118-4]; and (iv) produce complete and unredacted versions of the prescription records that the IPPs have produced to date. [ECF No. 116 at 2–3].

DFA No. 1² and Shire's RFP No. 2³ could lead to the production of communications between the Minors and their therapists, while the other requests are more narrowly tailored and will not result in the production of such communications. See [ECF Nos. 118-2, 118-3, 118-4, 118-5].

The legal issues are whether the Minors' medical records are relevant to the claims in this case, whether the Defendants' requests impose a burden that is disproportionate to the needs of the case, and whether the requested materials are privileged.

a. Relevance

"Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case." Fed. R. Civ. P. 26(b)(1).

Discovery "is designed to help define and clarify the issues." In re New England Compounding

Pharmacy, Inc. Prods. Liab. Litig., MDL 13-2419-FDS, 2013 WL 6058483, at *3 (D. Mass. Nov. 13, 2013) (quoting Oppenheimer Fund, Inc. v. Sanders, 437 U.S. 340, 351 (1978)).

The IPPs claim standing to sue and damages because they paid higher co-pays for Intuniv than they would have paid absent the Defendants' conduct, which the IPPs argue unreasonably

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² DFA No. 1 seeks authorization to obtain "complete medical records relating to the Minors from each health care provider who has previously consulted, treated, or examined any of the Minors for any of the conditions and/or symptoms for which the Minors, at some point, were prescribed Intuniv or generic Intuniv" and related to "the condition(s) and/or symptom(s) for which the Minors were at some point prescribed Intuniv or generic Intuniv." [ECF No. 118-5 at 1]. The Defendants narrowed this request to the time period from the date the Minors were diagnosed with ADHD to July 31, 2015. [ECF No. 118-10 at 2].

³ Shire's RFP No. 2 requests: "All documents concerning Your healthcare providers' decision(s) to prescribe Intuniv, Generic Intuniv, and/or any other drug or non-drug-based treatment for the same health condition for which You, at some point, were prescribed Intuniv or Generic Intuniv, including, for each healthcare provider contact or communication related to that health condition: (i) all documents related to every complaint, symptom, adverse reaction, or other injury, (ii) all medical reports and related documents (including all healthcare provider records, scans, lab reports, etc.), (iii) all documents concerning the treatment and/opinions of healthcare providers, and (iv) all medical claims, bills, payments, and related documents." [ECF No. 118-4 at 6–7].

restrained trade in a "relevant product market" comprised of "Intuniv and its generic equivalents." [ECF No. 39 ¶¶ 112, 117–32, 157]. The Defendants argue that the Minors' medical records may show that alternative treatments to brand or generic Intuniv were available, and that the availability of alternative treatments will inform the contours of the relevant product market and may provide evidence that the IPPs did not pay a higher price as a result of the challenged conduct. [ECF No. 117 at 2–3, 15].

"Determining the scope of a product market begins with examining the universe of products that are considered 'reasonably interchangeable by consumers for the same purposes." Flovac, Inc. v. Airvac, Inc., 817 F.3d 849, 854 (1st Cir. 2016) (quoting United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 395 (1956)). The Minors' medical records are therefore relevant to extent they contain information on alternative treatments. See Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 481 (1992) ("The proper market definition in this case can be determined only after a factual inquiry into the 'commercial realities' faced by consumers." (quoting United States v. Grinnell Corp., 384 U.S. 563, 572 (1966))); In re Loestrin 24 Fe Antitrust Litig., No. 1:13-md-2472-S-PAS, 2017 WL 1491911, at *6 (D.R.I. Mar. 15, 2017) ("[D]ocuments related to the parties' competing versions of the relevant product market are relevant."). Additionally, because the IPPs claim they were damaged through their insurance co-pays, the IPPs' insurance records and the Minors' pharmaceutical records are relevant to the issue of damages. See [ECF No 39 ¶ 117–32].

b. Burden and Privilege

The IPPs' undue burden and privilege objections are based primarily on the argument that the Defendants' requests may lead to the production of privileged psychotherapist-patient communications that could be used to annoy or embarrass the IPPs and the Minors. A party is

entitled to nonprivileged, relevant information if its requests are "proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1). A Court may, "for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense." Fed. R. Civ. P. 26(c)(1).

The laws of the five states on which the IPPs' claims are based, along with federal common law, recognize a psychotherapist-patient privilege. The Supreme Court has stated that the psychotherapist-patient privilege "covers confidential communications made to licensed psychiatrists and psychologists." <u>Jaffee v. Redmond</u>, 518 U.S. 1, 15 (1996). The privilege is "rooted in the imperative need for confidence and trust" and is intended to promote "frank and complete disclosure of facts, emotions, memories, and fears." <u>Id.</u> at 10. It covers communications that are made (1) confidentially, (2) between a psychotherapist or another covered person and the patient, and (3) in the course of diagnosis or treatment. <u>Silvestri v. Smith</u>, No. 14-13137-FDS, 2016 WL 778358, at *2 (D. Mass. Feb. 26, 2016) (citing <u>In re Grand Jury Proceedings (Violette)</u>, 183 F.3d 71, 73 (1st Cir. 1999)). The privilege protects "only the substance of communications' between the patient and his treatment provider" and "does not apply to 'facts regarding the occurrence of psychotherapy, such as the name of the

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⁴ The Defendants have not argued that the federal common law psychotherapist-patient privilege does not apply, although the claims here arise from state law causes of action. <u>See</u> Fed. R. Evid. 501 ("[I]n a civil case, state law governs privilege regarding a claim or defense for which state law supplies the rule of decision"); <u>Shea v. McGovern</u>, No. 1:08-12148-MLW, 2011 WL 322652, at *5 (D. Mass. Jan. 31, 2011) ("Questions of privilege in federal question cases are governed by federal law.") (citing Fed. R. Evid. 501).

psychotherapist or dates and costs of treatment," or "other non-communicative information such as the nature of any diagnosis or treatment for a mental health condition." Silvestri, 2016 WL 778358, at *2 (quoting Howe v. Town of N. Andover, 784 F. Supp. 2d 24, 34 (D. Mass. 2011); citing In re Adoption of Saul, 804 N.E.2d 359, 363-65 (Mass. App. Ct. 2004)). The IPPs claim that the Minors' medical records are also privileged under the laws of Florida, Massachusetts, Missouri, New York, and Wisconsin. See Fed. R. Evid. 501 ("[I]n a civil case, state law governs privilege regarding a claim or defense for which state law supplies the rule of decision."). The IPPs agree, however, that the "general analysis that courts employ with these laws [is] similar to the test federal courts employ with respect to the federal psychotherapist-patient privilege."

[ECF No. 114-1 at 16].

Most of the requests at issue will not lead to the discovery of psychotherapist-patient privileged communications because they request documents that will not contain communications between the Minors and their therapists.⁶ RFPs Nos. 1,3, and 4 relate to the IPPs' purchase of Intuniv, medications prescribed in lieu of Intuniv, and insurance benefits. [ECF No. 118-4 at 7–8]. Similarly, Shire's Interrogatories Nos. 1, 2, 3, 9, and 10 relate to the IPPs' purchase of Intuniv, medications prescribed in lieu of Intuniv, insurance claims, and damages. [ECF No. 118-3 at 5–10]. Those requests seek relevant information that does not fall within the psychotherapist-patient privilege, and the Court will grant the Defendants' motion to

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⁵ <u>See</u> Fla. Stat. § 90.503; Mass. Gen. Laws ch. 233 § 20B; Mo. Rev. Stat. § 337.055; N.Y. C.P.L.R. § 4507; Wis. Stat. §§ 146.82, 905.04.

⁶ To the extent that the IPPs have asserted broader protections for health records, the IPPs cannot maintain those protections because they have placed the Minors' treatment for ADHD, the availability of alternative treatments, their insurance policies, and the economics of their pharmaceutical purchasing practices at issue in this case. See In re New England Compounding Pharm., 2013 WL 6058483, at *13 ("In most cases, when a patient puts his health at issue in litigation, the privilege is waived." (citing In re Asbestos Prods. Liab. Litig., 256 F.R.D. 151, 155 n. 10 (E.D. Pa. 2009))).

compel with respect to those requests. <u>See Silvestri</u>, 2016 WL 778358, at *2 (holding that facts regarding the occurrence of psychotherapy and the names of treatments were not privileged).

Although the Defendants expressly disclaim any interest in "sensitive communications between the Minors and their therapists," [ECF No. 117 at 11], DFA No. 1 and RFP No. 2 could lead to the production of privileged communications. See supra notes 2–3. The Minors' medical records are relevant and must be produced, but the Court will allow the IPPs to collect the medical records and redact privileged communications that do not relate to alternative treatments or the cost of Intuniv. Further, the scope of the production is limited to records from the year in which the minor at issue was diagnosed with ADHD through 2015. The Court will therefore quash the subpoena issued to Dr. Auster and order that the parties work collaboratively towards the production of medical records with appropriate redactions and limited to the post-diagnosis timeframe.⁷

The Court will also restrict the scope of DFAs Nos. 4 and 5, which seek authorizations to obtain "complete pharmacy or drug store records with respect to any drugs prescribed for each of the Minors" and "complete health insurance records" for the previous 10 years. [ECF No. 118-5 at 3]. Given that the IPPs damages are based upon co-pays that varied by drug, and that a myriad

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⁷ DFAs Nos. 2 and 3 request "hospital records relating to the Minors (including diagnostic tests such as MRIs, CAT scans, EKGs, EEGs, x-rays, and technicians' reports of such diagnostic tests) from each hospital, clinic, or other health care facility at which any of the Minors were treated" and "medical records for any laboratory testing related to any of the conditions and/or symptoms for which the Minors, at some point, were prescribed Intuniv or generic Intuniv." [ECF No. 118-5 at 3]. As with DFA No. 1, DFAs Nos. 2 and 3 are "directed at records for consultation, treatment, or examination for the condition(s) and/or symptom(s) for which the Minors were at some point prescribed Intuniv or generic Intuniv, regardless of whether that particular consultation, treatment, or examination resulted in an Intuniv or generic Intuniv prescription." [ECF No. 118-5 at 3]. The parties must work collaboratively towards the production of relevant medical records from healthcare providers and hospitals, including any relevant laboratory testing, but Plaintiffs need not solicit such laboratory records that are not in the possession of care providers or hospitals.

of factors could affect the amount of the IPPs' co-pays and the availability of alternative treatments, the Court will grant Defendants motion to compel authorizations for the pharmaceutical and health insurance records. The Court will, however, limit the date range for pharmacy and health insurance records to the year in which the minor was diagnosed with ADHD through 2015.

II. CONCLUSION

For the reasons stated, ECF Nos. 114 and 116 are resolved as follows:

- 1. The IPPs shall provide authorizations allowing Defendants to obtain complete pharmacy and health insurance records as requested by DFAs Nos. 4 and 5 from the year in which the minor was diagnosed with ADHD through 2015 within fourteen (14) days of this order.
- 2. The IPPs shall provide responses to Shire's Interrogatories Nos. 1, 2, 3, 9, and 10 within fourteen (14) days of this Order.⁸
- 3. The IPPs shall produce any documents in their possession or custody that are responsive to Shire's RFPs Nos. 1, 3, and 4 within fourteen (14) days of this order.
- 4. The IPPs shall obtain and produce all records responsive to Shire RFP No. 2 or which could be collected pursuant to an authorization responsive to DFA Nos. 1 or 2 with appropriate redactions. Any relevant medical records presently in the possession or custody or the IPPs must be produced within fourteen (14) days of this order. The IPPs must request relevant documents from the Minors' healthcare providers within seven (7) days of this order and then undertake a prompt review and production of responsive documents.
- 5. The IPPs shall produce complete, unreducted versions of the pharmaceutical records that the IPPs have previously produced within seven (7) days of this Order.
- 6. The IPPs' request for fees and costs is denied.
- 7. All medical records shall be treated as "confidential outside counsel only" information under the protective order. [ECF No. 98].

⁸ In responding to interrogatory 9(i), which demands "a quantification of any money damages You allege that You suffered," it is sufficient for the IPPs to respond that they believe they overpaid for Intuniv, if they cannot provide a more precise amount. [ECF 118-3 at 9].

SO ORDERED.

December 14, 2018

/s/ Allison D. Burroughs ALLISON D. BURROUGHS U.S. DISTRICT JUDGE